IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**David Snyder**	
Application No.	**:**	**10/537,792**	**From PCT/IB03/05812**
Filed	**:**	**June 6, 2005**	
For :		**EXTERNAL DEFIBRILLATOR WITH SHOCK ACTIVATED BY CESSATION OF PRECORDIAL COMPRESSIONS**	

APPEAL BRIEF

On Appeal from Group Art Unit 3762

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Attorn ey for Appellant

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I. REAL PARTY IN INTEREST

The real party in inte rest is Koninklijke Philips Electro nics N.V., Eindhoven, The Ne therlands by virtue of an assignment r ecorded June 6, 2005 at reel 017398, frame 0300.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STAT US OF CLAIMS

Claims 1-24 have been canceled and Claims 30-45 have been withdrawn. Claims 25-29 and Claims 46-57 are pending in the application. Claims 25-29 stand finally rejected and Claims 46-57 were withdrawn by the Examiner in the Office action mailed December 10, 2008. The claims being appealed are Claims 25-29 and Claims 46-57.

IV. S TATUS OF AMENDMENTS

No amendments were filed in r esponse to the final rejection mailed December 10, 2008. A Notice of Appeal was filed on February 10, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per independent Claims 25, 46, and 54 is a method for delivering a defibrillation shock using a defibrillator in conjunction with the administration of cardiopulmonary resuscitation (CPR). External defibrillators such as hospital (ALS) defibrillators and automatic external defibrillators (AEDs) are capable of treating sudden cardiac arrest, known clinically as ventricular fibrillation (VF), by a combination of electrotherapy which restarts a normal heartbeat and CPR which forces oxygenated blood through the vascular system and particularly to the brain during resuscitation. The typical rescue protocol of an AED has two parts, an electrotherapy part and a CPR part. During the electrotherapy part, the patient's ECG signal is acquired by the AED and analyzed to determine whether the patient is in VF. If a shockable rhythm is identified by this analysis, the AED commences preparation for shock delivery, including charging the high voltage capacitor which delivers the shock energy. The shock can be delivered automatically by the AED or a rescuer can trigger the shock by pressing a shock delivery button on the AED. During the CPR part of the rescue, the AED halts the electrotherapy activities and pauses for a period of time during which CPR is performed on the patient. Generally the AED will guide the rescuer in the delivery of precordial

compressions such as by producing a metronome tone at the rate at which the chest compressions are to be applied. The rate of chest compressions prescribed by the American Heart Association for CPR is 100 compressions per minute. When the CPR interval has ended, the AED will return to its electrotherapy activities, examining the ECG waveform for a shockable rhythm and delivering a shock if needed.

When rescuing a victim from sudden cardiac arrest, time is of the essence, for the brain is deprived of blood during VF and disability and death will result if blood flow is not restored within 9-12 minutes of the onset of VF. The present invention is directed to quickly delivering needed electrotherapy and CPR with minimal delay, in particular, the transition from CPR to electrotherapy. As stated on page 2, lines 11-15 of the present application (paragraph [0004] of the US patent pub. 2006/0116724):

> When CPR is performed, some level of circulation is restored artificially, which can improve the chances of survival. When CPR is discontinued to allow the AED to analyze the heart rhythm (via the ECG), circulation is once again stopped. A long interval between discontinuation of CPR and shock delivery will decrease the chance of survival. It is this second interval that is addressed by this invention.

As the title of the application indicates, the present invention shortens the interval between the discontinuation of CPR and shock delivery by sensing the cessation of the CPR precordial compressions,

and using this recognition to trigger the events leading to shock delivery. In the prior art, as typified by the cited Cole et al. patent (US Pat. 5,611,815), the defibrillator will pause its electrotherapy activities for a programmed period of time, generally one to three minutes, to allow CPR to be performed by the rescuer. When this CPR interval times out, the defibrillator will resume monitoring the ECG waveform for a shockable rhythm. See Cole et al. at col. 5, lines 58-62. It is presumed that the rescuer is performing CPR precordial compressions at the prescribed rate and compression depth during this time. But delivering 100 vigorous chest compressions per minute continuously for several minutes can be very taxing on the rescuer, particularly a layperson rescuer who may not be trained or experienced in doing so. Experience has shown that at times the rescuer will pause for rest during the CPR interval or cease CPR before the CPR interval has timed out. It is such premature cessation of CPR which is recognized by an implementation of the present invention to commence immediate resumption of electrotherapy. Similarly, if the rescuer delivers CPR longer than the preprogrammed interval, an implementation of the present invention will recognize the extension and ultimate cessation of precordial compressions and trigger the resumption of electrotherapy at that time.

The pending claims are directed to three ways in which the cessation of precordial compressions may be detected and the time to shock delivery foreshortened. Claim 25 identifies a cessation of precordial compressions from the same ECG signal used by the electrotherapy part of the defibrillator for shockable rhythm analysis. In Claim 25 the ECG signal is analyzed for signal corruption, the signal corruption caused by a firm CPR chest compression. The identification of this ECG signal corruption indicates that CPR is still being performed, and an absence of signal corruption will trigger electrotherapy activities including ECG analysis to determine if a shock is needed, and the delivery of a defibrillation shock. Claim 46 specifies that the indication of cessation of precordial compressions during CPR will be the basis for arming the defibrillator for shock delivery. In Claim 54 and its progeny a physiological signal from a body sensor, such as an ECG or motion signal, is used to detect the cessation of precordial compressions.

Claim 25, directed to a method for delivering a defibrillation shock using a defibrillator, is supported in the specification by the text from page 12, line 17 through page 14, line 6 and by FIG. 4. As stated on page 12, lines 17-19, FIG. 4 shows a sequence of steps performed during an interval of CPR treatment. Sensors are attached to the patient in step 100 which enables an ECG input signal from the patient to be monitored. The

ECG signal is monitored during administration of CPR for signal corruption as stated on page 12, lines 21-22. In step 120 of FIG. 4 the defibrillator determines if the CPR treatment has stopped from the ECG input signals from a sensor as described from page 12, line 24 through page 13, line 1. The detection of VF by the signal processing of step 140 as specified on page 13, lines 1-4 determines the need for a defibrillation shock. This identification of the need for a defibrillation shock results in the delivery of a shock as described on page 13, line 22 through page 14, line 5, with reference to step 200 of FIG. 4.

Claim 46 also describes a method for delivering a defibrillation shock using a defibrillator. Sensors are attached to the patient and CPR treatment is started as shown in FIG. 4. As stated on page 7, lines 15-20, the delivery of electrical therapy (a shock) is triggered by a detection of the cessation or absence of CPR precordial compressions. As shown by the defibrillator operating sequence beginning on page 5, line 9, the detected cessation of precordial compressions which marks the end of CPR results in the precharging of the therapy capacitor to an intermediate level. If the ECG analysis indicates VF (a shockable rhythm) the defibrillator finishes charging the capacitor and the shock button is armed for shock delivery, as stated on page 5, lines 17-20.

The method for delivering a defibrillation shock using a defibrillator as described in Claim 54 is supported by FIG. 4 which begins in step 100 by attaching sensors to a patient to detect physiological signals of the patient. CPR treatment is given by the application of precordial compressions as stated on page 12, lines 22-24. In step 120 the defibrillator monitors for the termination of the CPR precordial compressions. The defibrillator of FIG. 2 does this by a body sensor 12 coupled to a mechanical disturbance detector 10 which detects the movement of the patient during the delivery of CPR precordial compressions, as stated on page 8, lines 7-9. The ECG signals are obtained from electrodes 22 and 24 as stated on page 8, lines 11-13 and are analyzed to determine whether a defibrillation shock is needed in step 140 of FIG. 4. If the analysis determines that a shock is needed, a shock is delivered as described on page 13, lines 22 through page 14 line 5 and in step 200 of FIG. 4.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 46-57 were properly withdrawn from consideration as being directed to a non-elected invention;

B. Whether Claims 25-28[1] were correctly rejected under 35 U.S.C. §102(b) as anticipated by US Pat. 5,611,815 (Cole et al.); and

C. Whether Claim 29 was correctly rejected under 35 U.S.C. §103(a) as being unpatentable over Cole et al. in view of US Pat. appl. pub. US 2004/0162585 (Elghazzawi et al.).

VII. ARGUMENT

A. Withdrawal of Claims 46-57 from consideration

In the final rejection, Claims 25-29 were said to be a combination distinct from the subcombination of Claims 46-53. The basis for this determination was that Claims 25-29 were said to have the capability of utilizing an implantable defibrillator in order to deliver a defibrillation shock, rather than an AED as recited in Claims 46-53. It should first be noted that all of Claims 25-29 and 46-53 are drawn to a method for delivering a defibrillation shock using a defibrillator. Each of the claims is specifically directed to using a defibrillator which has both a CPR interval and an electrotherapy interval. Only an external defibrillator can have both CPR and electrotherapy modes. As the title of the application states, the invention is an external defibrillator with shock activated by

Note 1: The Examiner's rejection refers to Claims 26-28. Since Claim 25 was unmentioned, it is assumed that this rejection was intended to be of Claims 25-28.

cessation of precordial compressions. An AED is an external defibrillator, and both its CPR and electrotherapy treatments are provided from outside the body of the patient. An implantable defibrillator is fully contained within the body of a patient and is entirely self-contained. It does not and cannot have a CPR mode because it has no way of interacting with the entirely separate and independent external application of CPR. The implanted defibrillator will continually perform its function of monitoring the patient's ECG and delivering a shock if called for, independent and unmindful of external activities such as CPR. Simply stated, it is impossible to perform any of the methods of these claims with an implantable defibrillator. Consequently it is respectfully submitted that there is no basis for determining that Claims 25-29 and Claims 46-53 are directed to distinct inventions.

Claims 25-29 were said to be a subcombination distinct from the combination of Claims 54-57. The basis for this determination was that Claims 54-57 do not require analyzing an ECG signal for signal corruption but rather monitoring and analyzing ECG signals for cessation of precordial compressions. It is noted that both Claim 25 and Claim 54 call for monitoring a physiological signal to detect a cessation of precordial compressions. In Claim 54 this limitation is recited exactly in this manner. In Claim 25 the physiological signal is specified as an ECG

signal which may exhibit signal corruption. The specification teaches two ways to detect manifestation of precordial compressions, sensing patient motion or ECG signal corruption, both of which result from chest compressions. As the application shows, these two factors may be correlated to identify precordial compression. And as stated on page 8, lines 20-23, the mechanical disturbance detector and the ECG can be merged as one component. Claims 25 and 54 are no more distinct than are an independent claim specifying the use of a physiological signal and a dependent claim which specifies that the physiological signal is an ECG signal. If the two claims were the same, the rule of claim differentiation would come into play. It does not with these claims. Accordingly it is respectfully submitted that Claims 25-29 and Claims 54-57 are not drawn to patentably distinct inventions.

The claims which were the subject of the initial restriction requirement, Claims 30-45 which were drawn to a method for applying electrotherapy and a defibrillator, have been withdrawn from the case. The claims currently pending are all directed to a method for delivering a defibrillation shock using a defibrillator, and all the claims revolve around detecting the cessation of precordial compressions as a trigger to delivery of a defibrillation shock. It is respectfully requested that the Board overturn the withdrawal of Claims 46-57 from this application.

The analysis of the patentability of Claims 46-57 over the references applied to the other pending claims, Cole et al. and Elghazzawi et al., is straightforward. It is seen that Claims 46-57 are all supported by the December 13, 2002 priority specification and drawings. This means that Elghazzawi et al., with its February 19, 2003 priority date, is ineffective as a reference against these claims. Thus, the patentability of Claims 46-57 can only be measured against the teaching of Cole et al. Cole et al. only provide a defibrillator with a preprogrammed CPR pause. They do not detect an indication of CPR precordial compression cessation during CPR as called for by the second step of Claim 46 and by the third step of Claim 54. Furthermore, Cole et al. do not show or suggest triggering shock delivery from a detection of the cessation of precordial compressions. (Neither do Elghazzawi et al., for that matter, as all they do is go into a foreground mode of ECG analysis at the end of CPR.) For these reasons it is respectfully submitted that Cole et al. cannot anticipate or render Claims 46 and 54 and their dependent claims unpatentable.

B. Rejection of Clai ms 25-28 under 35 U.S.C. §10 2(b) as anticipated by Cole et al.

Claim 25 describe s a method for delivering a defi brillation shock using a defib rillator, th e method comp rising the steps o f (a) having the

defibrillator initiate a cardio-pulmonary resuscitation (CPR) interval; (b) prior to an end of the cardio-pulmonary resuscitation (CPR) interval, analyzing the ECG signal for signal corruption and, if a cessation or absence of CPR precordial compressions is indicated by substantially no signal corruption; (c) analyzing an ECG signal prior to the end of the originally initiated cardio-pulmonary resuscitation (CPR) interval to determine if a defibrillation shock is needed; and, (d) delivering a defibrillation shock if the analyzing step indicates that a defibrillation shock is needed. As previously mentioned, the present invention revolves around detecting the cessation or absence of CPR precordial compressions and using this event to trigger actions leading to shock delivery. Cole et al. mention CPR in only a single paragraph of their patent, that in column 5, lines 58-62. All that is said there is that their defibrillator has a programmable pause to permit CPR to be performed. There is nothing in Cole et al. relating to detecting the cessation of precordial compressions of CPR. Accordingly it is respectfully submitted that Cole et al. cannot anticipate Claim 25 or its dependent Claims 26-29.

In the final rejection the Examiner disregarded the limitation "for signal corruption and, if a cessation or absence of CPR precordial compressions is indicated by substantially no signal corruption" of Claim 25. The basis for disregarding this limitation was that it was an intended

use recitation which does not result in a structural difference. However it is respectfully noted that the claim is question is a method claim, not an apparatus claim. This method claim recites steps, each including a function or action taken in that step. What the Examiner has done is disregard the functional limitation of analyzing the ECG signal for no signal corruption to indicate the cessation of precordial compressions. It is respectfully submitted that it is improper to disregard the functional limitation of a method claim. Furthermore, even if this were an intended use, there is no showing that the Cole et al. defibrillator is capable of detecting a cessation of CPR precordial compressions by an absence of signal corruption or by any other means. For these reasons it is respectfully submitted that Cole et al. cannot anticipate Claims 25-29.

C. Rejection of Claim 29 under 35 U.S.C. §103(a) as being unpatentable over Cole et al. in view of US Pat. appl. pub. US 2004/0162585 (Elghazzawi et al.)

Claim 29 describes the method of Claims 25, wherein the defibrillation shock is provided about 10 seconds or less after the cessation of precordial compressions. It is noted that the Elghazzawi et al. application has a priority date of February 19, 2003. The present application claims the benefit of two priority documents, no. 60/433,375 of December 13, 2002 and no. 60/476,981 of June 9, 2003. The present

specification and drawings are identical to those of the December 13, 2002 application, with two substantive exceptions. In the previous Amendment in this case, a voice circuit/speaker 41 was added to page 6 from the 2003 application, and the sensor 12 on page 10 was said to include the accelerometer mentioned in the 2003 application. However neither the voice circuit/speaker nor the accelerometer are mentioned in the pending claims. Accordingly it is respectfully submitted that Claim 29 is fully supported by and has the priority date of the December 13, 2002 application. This means that Elghazzawi et al., with its February 19, 2003 priority date, is ineffective as a reference against Claim 29.

As previously mentioned, Cole et al. only call for a preprogrammed CPR pause. There is no mention of the cessation of precordial compression or of the time to any other subsequent operations of their defibrillator. Elghazzawi et al. describe a defibrillator which runs an "ECG background analysis task 22" during the CPR interval. Elghazzawi et al. are looking for an interval of ECG signals of "X seconds" between chest compressions when a clean ECG signal strip can be obtained for shockable rhythm analysis. But as pointed out in the previous Amendment in this case, this search is illusory. An ECG strip suitable for rhythm analysis is at least four seconds long. See, *e.g.*, page 5, lines 3 and 15 of the present specification. With CPR being applied at 100

compressions per minute, a suitably long 4-second strip will not be found until CPR is terminated.

But even if a suitably long strip were found, Elghazzawi et al. do not use it to trigger shock delivery. Instead, if a shockable rhythm is found, they alert the rescuer to the presence of a shockable rhythm and switch the defibrillator to the ECG foreground analysis state 42. See Elghazzawi et al. at the concluding sentence of paragraphs [0025], [0027], and [0029]. Elghazzawi et al. then do a second analysis in the foreground state 42 for the presence of a shockable rhythm, which might then lead to shock delivery. This is no better than the prior art approach, which waits until CPR is concluded before resuming ECG acquisition, analysis, and possible preparation for shock delivery. It is respectfully submitted that, even if Elghazzawi et al. were effective as a reference in this application, it still would not render Claim 29 or Claim 25 unpatentable.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 46-57 are not patentably distinct from Claims 25-29 and should not be withdrawn from this application. It is also respectfully submitted that Claims 25-28 are not anticipated by Cole et al. and that Claim 29 is

patentable over Cole et al. and Elghazzawi et al. It is further respectfully submitted that Claims 46-47 are patentable over the cited references. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the December 10, 2008 Office action being appealed.

R espectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 25-29 and Claims 46-57 are the claims involved in the appeal.

1. - 24. (canceled)

25. (rejected) A method for delivering a defibrillation shock using a defibrillator, the method comprising the steps of:

(a) having the defibrillator initiate a cardio-pulmonary resuscitation (CPR) interval;

(b) prior to an end of the cardio-pulmonary resuscitation (CPR) interval, analyzing the ECG signal for signal corruption and, if a cessation or absence of CPR precordial compressions is indicated by substantially no signal corruption;

(c) analyzing an ECG signal prior to the end of the originally initiated cardio-pulmonary resuscitation (CPR) interval to determine if a defibrillation shock is needed; and,

(d) delivering a defibrillation shock if the analyzing step (c) indicates that a defibrillation shock is needed.

26. (rejected) The method of Claim 25, wherein step (c) includes charging t he def ibrillator pri or to th e end of the originally initiated cardio-pulmonary resuscitation (CPR) interval.

27. (rejected) The method of Claim 25, wherein step (c) includes determining whether a disturbance a ssociated with the cardio-pulm onary resuscitation (CPR) interval is detected ; and, if there is s ubstantially no disturbance, delivering the defibrillation shock if needed.

28. (rejected) The method of Claim 25, furthe r comprising the step of notifying an operator of the defibrillator prior to delivering the defibrillation shock.

29. (rejected) The method of C laim 25, wherein the defibrillation shock is provid ed a bout 10 s econds or less after the cessation of precordial compressions.

30. - 45. (withdrawn)

46. (withdrawn) A method for de livering a defibrillation shock using a defibrillator, the method comprising the steps of:

prompting a start of a CPR therapy interval;

detecting an indication of CPR precordial compression cessation during the CPR therapy interval; and,

arming the AED for defibrillation shock delivery based on the detected cessation of precordial compressions detected during the CPR therapy interval.

47. (withdrawn) The method of Claim 46, wherein the arming step is complete in less than about 10 seconds from detection of the cessation of precordial compressions.

48. (withdrawn) The method of Claim 46, wherein the indication is based upon a predetermined end of the CPR therapy interval.

49. (withdrawn) The method of Claim 48, wherein the arming step includes initiating a charging of the high voltage energy source prior to the predetermined end of the CPR therapy interval.

50. (withdrawn) The method of Claim 48, wherein the arming step includes completing a charging of a high voltage energy source of

the defibrillator prior to the predetermined end of the CPR therapy interval.

51. (withdrawn) The method of Claim 48, further comprising the steps of:

obtaining an ECG signal from the ECG detector prior to the predetermined end of the CPR therapy interval; and

determining whether the ECG signal is corrupted by CPR activity, wherein the arming step is further based on determining an uncorrupted ECG signal.

52. (withdrawn) The method of Claim 46, wherein the indication of CPR cessation includes a signal generated by CPR activity.

53. (withdrawn) The electrotherapy method of Claim 52, further comprising the steps of:

obtaining an ECG signal from the ECG detector prior to the CPR cessation; and

determining whether the ECG signal is uncorrupted by CPR activity; wherein the arming step is further based on the determining step.

54. (withdrawn) A method for deliv ering a defibrillation shock using a defibrillator, the method comprising the steps of:

coupling a plurality of sensors to the patient's b ody to de tect physiological signals of the patient;

initiating a predeterm ined CPR therapy interval during w hich precordial compressions are to be administered to the patient;

monitoring a physiolo gical signal received from at least one o f the sensors to detect a cess ation of pr ecordial co mpression ad ministration prior to the end of the predetermined CPR therapy interval;

upon de tecting a cessation of precordial com pression administration prior to the end of the predeter mined therapy i nterval, obtaining ECG signals from a plurality of the sensors;

analyzing the obtain ed ECG s ignals to determin e whether a defibrillation shock is needed; and

if the analyzing step deter mines tha t a defibrillation shock is needed, delivering a defibrillation shock to the patient thr ough a plurality of the sensors.

55. (withdrawn) The method of Cl aim 54, where in one of the sensors d etects a signal ind icative of patient moveme nt due to CPR motion,

wherein the signal indicative of patient movement is used in the detecting step.

56. (withdrawn) The method of Claim 54, wherein one of the sensors detects a signal indicative of ECG signal corruption from CPR activity,

wherein the signal indicative of ECG signal corruption is used in the detecting step.

57. (withdrawn) The method of Claim 54, further comprising the step of initiating charging of a high voltage energy source prior to the predetermined end of the predetermined CPR therapy interval.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.